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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/990,497	11/21/2001	Robert Waranis	RPS6096-US	3407

7590 09/09/2003

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EXAMINER	
JOYNES, ROBERT M	
ART UNIT	PAPER NUMBER
1615	9

DATE MAILED: 09/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Appli ant(s)	
	09/990,497	WARANIS ET AL.	
	Examiner	Art Unit	
	Robert M. Joynes	1615	

-- The MAILING DATE of this communication appears on the cover sheet with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 August 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5 and 6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt is acknowledged of applicants' Election dated August 22, 2003.

Election/Restrictions

Applicant's election with traverse of species A in Paper No. 8 is acknowledged. The traversal is on the ground(s) that no undue burden exists to examine all the claims. This is not found persuasive. It is the position of the Examiner that 3 distinct solvent systems are claimed and each would have different properties and different delivery of the active agent.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 4-6, 9, 10, 12-14 and 17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for sodium l-lactate, does not reasonably provide enablement for lactate salt or alkaline metal lactate salt. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Claim 1 recites a composition comprising acetaminophen and a lactate salt. Claim 9 recites a composition comprising acetaminophen and a alkali metal lactate salt. Upon review of the Specification, the Examiner noted that only sodium l-lactate was used as the solution system in the composition, not all latate salts

or any other lactate salt. Therefore, while enabled for sodium l-lactate, the specification does not reasonably provide enablement for all lactate salts or even the more specific alkali metal lactate salts.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,

2) the amount of direction or guidance provided,

3) the presence of absence of working examples,

4) the nature of the invention,

5) the state of the prior art,

6) the relative skill of those in the art

7) the predictability of the art, and

8) the breadth of the claims.

Applicant fails to set forth the criteria that defines what lactate salts are suitable for the composition to form a solution with acetaminophen. Additionally, Applicant fails to provide information allowing the skilled artisan to ascertain these compounds without undue experimentation. In the instant case, only examples with sodium l-lactate are set forth, thereby failing to provide sufficient working examples. It is noted that these

examples are neither exhaustive, nor define the class of compounds required. The pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. The instant claims read on all lactate salts, necessitating an exhaustive search for the embodiments suitable to practice the claimed invention. Applicants fail to provide information sufficient to practice the claimed invention, absent undue experimentation.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 6, 9, 12-14 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yu et al. (US 5071643) in combination with Honour et al. (US 5529923). Yu teaches a solvent system for acetaminophen comprising acetaminophen (Col. 5, lines 13-17), polyethylene glycol (Col. 4, line 41 – Col. 5, line 7; Col. 6, lines 23-

35), as well as hydroxide ions, water, glycerin and polyvinyl pyrrolidone (Col. 7, lines 10-12). The system can also include suitable preservatives, stabilizing, or wetting agents and coloring substances (Col. 9, lines 29-32). The solvent system and solution are suitable for soft gel encapsulation (Col. 10, lines 39-49). Yu does not expressly teach the inclusion of a lactate salt.

Honour teaches a solution composition in which buffering agent, tonicity agents and wetting agents such s a sodium lactate are used (Col. 8, lines 56-64). Honour teaches that sodium lactate is a known additive for solution formulations.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to add excipients such as preservatives, stabilizing, or wetting agents and coloring substances to a solution of acetaminophen.

One of ordinary skill in the art would have been motivated to do this maintain a solution at approximate physiological conditions.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 2, 3, 10, 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yu et al. (US 5071643) in combination with Honour et al. (US 5529923) in combination with Veech (US 6020007). The teachings of YU and Honour are discussed above. Yu and Honour do not expressly teach that the lactate salt is the l-lactate salt.

Veech teaches that the l-form of the salt is preferred in physiological conditions (Col. 2, lines 52-62).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to incorporate the l-form of the lactate salt in the solvent system

One of ordinary skill in the art would have been motivated to do this maintain a solution that is suitable and preferred in the physiological environment to which it is administered.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 4, 5, 7, 8, 12, 13, 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yu et al. (US 5071643) in combination with Honour et al. (US 5529923) in combination with Veech (US 6020007) in combination with Shelley et al. (US 5505961). The teachings of Yu, Honour and Veech are discussed above. These references do not expressly teach the inclusion of potassium acetate.

Shelley teaches a clear solvent system similar to Yu's system but comprising potassium acetate (Col. 3, lines 21-27). Shelley teaches that the potassium acetate aids in the solubility of acetaminophen.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to incorporate potassium acetate into a solvent system solution with acetaminophen.

One of ordinary skill in the art would have been motivated to do this to aid in the solubility of the drug.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Joynes whose telephone number is (703) 308-8869. The examiner can normally be reached on Mon.-Thurs. 8:30 - 6:00, alternate Fri. 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Robert M. Joynes
Patent Examiner
Art Unit 1615
September 8, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600